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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Hideaki Yamaoka

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HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT

PAPER NUMBER

1795

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,295	Applicant(s) YAMAOKA ET AL.	
	Examiner ALEX NOGUEROLA	Art Unit 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01/21/2010 (amndt.).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 12-24 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4 and 5 is/are allowed.
- 6) ☒ Claim(s) 1,8-10, 20-24 is/are rejected.
- 7) ☒ Claim(s) 2,3,6,7 and 12-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/30/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's amendment of January 21, 2010 does not render the application allowable.

Response to Arguments

2. Applicant's arguments with respect to claims 1-10 and 12-24 have been considered but are moot in view of the new grounds of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 8-10, 20, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited Yamamoto et al. US 6,471,839 B1 (“Yamamoto II”).

Addressing claim 1, Yamamoto II discloses an analytical instrument having improved arrangement of reagent portion (see the abstract), the analytical instrument comprising:

a flow path (12) for moving a sample containing blood cells (col. 01:29-34);

an introduction port (10) for introducing the sample into the flow path (col. 06:54-57);

an electron detection medium (4,5) for obtaining information necessary for analyzing an analysis target component contained in the sample in relation with an amount of electrons transferred (col. 06:29-43 and col. 01:20-29);

a reagent portion (21) arranged directly in the flow path the reagent portion containing an electron mediator for supplying an electron taken from the analysis target component in the sample to the electron detection mediator, at least part of the reagent portion being positioned adjacent to the introduction port (Figure 5; col. 03:30-36; col. 06:01-04; and col. 08:51-65); and

an additional reagent portion (22) provided separately from said reagent portion and containing an oxidoreductase for taking an electron from the analysis target component contained in the sample and supplying the electron to the electron mediator (Figure 5; col. 03:30-36; and col. 08:66 – col. 09:06);

wherein said reagent portion, the additional reagent portion, and the electron detection medium are provided on a same plane (Figure 5).

Addressing claim 8, for the additional limitation of this claim see col. 06:29-44.

Addressing claim 9, it should be first noted that this claim just appears to add an intended use to underlying claim 8. In any event, the additional limitation of this claim is taught by Yamamoto. See col. 09:15-23 and col. 07:53-64.

Addressing claim 10, for the additional limitation of this claim see col. 08:66 – col. 09:06.

Addressing claim 23, for the additional limitation of this claim see col. 04:45-49 and note “glucose oxidase”. Also see col. 01:29-35.

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5. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. US 6,471,839 B1 ("Yamamoto II") in view of Charlton et al. US 5,798,031 ("Charlton").

Addressing claim 24, Yamamoto also discloses an analytical instrument as set forth in underlying claim 1. See the rejection of claim 1 under 35 U.S.C. 102(b) above. Although not stated as such, the flow path is dimensioned so that it would generate a capillary force. See col. 06:50-57 and col. 07:33-36 in Yamamoto and col. 05:67 – col. 06:04 in Charlton.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamamoto et al. US 6,471,839 B1 ("Yamamoto II") in view of Nagakawa et al. US 7,390,391 B2 ("Nagakawa").

Yamamoto II discloses an analytical instrument as set forth in claim 20. See the rejections of claims 1, 10, and 20 under 35 U.S.C. 102(b) above.

Although Yamamoto II discloses a variety of possible enzymes, including glucose oxidase (col. 04:45-49), and electron mediators (col. 05:63–67), Yamamoto II does not

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mention using and an oxidase such as PQQGDH or a Ru complex as electron mediator.

Nagakawa discloses an electrochemical analytical instrument comprising an oxidoreductase, such as PQQGDH, α GDH or CyGDH and a Ru complex as electron mediator. See the abstract and col. 03:44 – col. 04:56. In light of Nagakawa, using α GDH or CyGDH as oxidoreductase, or a Ru complex as an electron mediator in the analytical instrument of Yamamoto is just optimizing the reagent for the target analytes. In other words it is substitution known reagent ingredients for those disclosed by Yamamoto II with predictable results.

Allowable Subject Matter

8. Claims 2, 3, 6, 7, and 12-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. Claims 4 and 5 are allowed.

10. The following is a statement of reasons for the indication of allowable subject matter:

a) Claim 2 – the combination of limitations requires that “the reagent portion is arranged upstream from the electron detection medium in a direction of flow of the sample while being separated from the electrode detection medium” and that the “... reagent portion, the additional reagent portion, and the electron detection medium are provided on a same plane.”

In Yamamoto II the reagent portion (21) is partially arranged upstream from the electron detection medium (4,5) in a direction of flow of the sample, but is not separated from the electron detection medium as it overlaps it. See Figure 5.

b) Claim 3 depends from allowable claim 2.

c) Claim 4 – the combination of limitations requires (i) “a flow path for moving a sample containing blood cells; an introduction port for introducing the sample into the flow path...”, (ii) “wherein the reagent portion is arranged upstream from the electron detection medium in a direction of flow of the sample while being separated from the electron detection medium”, and (iii) “wherein center-to-

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center distance between the reagent portion and the electron detection medium is so set that, when the sample contains the analysis target component in maximum amount of a predetermined detection range, electron transfer from the maximum amount of analysis target component to the electron mediator is substantially completed before the electron mediator becomes able to supply electrons to the electron detection medium.”

In Yamamoto US 6,436,255 B2 it may be inferred that it is desirable for blood cells to be filtered from a blood sample before the sample reaches sample port (10). See col. 04:19-25 and col. 08:30-38.

In Yamamoto US 6,471,839 B1 the reagent portion (21) is partially arranged upstream from the electron detection medium (4,5) in a direction of flow of the sample, but is not separated from the electron detection medium as it overlaps it. See Figure 5.

d) Claim 5 – the combination of limitations requires (i) “a flow path for moving a sample containing blood cells; an introduction port for introducing the sample into the flow path...”, (ii) “wherein the reagent portion is arranged upstream from the electron detection medium in a direction of flow of the sample while being separated from the electron detection medium”, and (iii) “wherein the content of the electron mediator in the reagent portion is so set that, when the sample contains the analysis target component in maximum amount of a predetermined

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detection range, the electron mediator can receive all the electrons taken from the maximum amount of analysis target component.”

In Yamamoto US 6,436,255 B2 it may be inferred that it is desirable for blood cells to be filtered from a blood sample before the sample reaches sample port (10). See col. 04:19-25 and col. 08:30-38.

In Yamamoto US 6,471,839 B1 the reagent portion (21) is partially arranged upstream from the electron detection medium (4,5) in a direction of flow of the sample, but is not separated from the electron detection medium as it overlaps it. See Figure 5.

e) Claim 6 – the combination of limitations requires the electron detection medium to contain a color former. Yamamoto II discloses an electrochemical biosensor. There is no suggestion of including a color former in the electron detection medium.

f) Claim 7 depends from allowable claim 6.

g) Claim 12 – the combination of limitations requires the additional reagent portion to be arranged between the reagent portion and the electron detection medium in a direction of flow of the sample in the flow path. In Yamamoto the additional reagent portion (22) is side-by-side with the reagent portion (21). See Figure 5.

h) Claim 13-19 depend from allowable claim 12.

i) Supplementary European Search Report for Application Number EP 05703392 ("Search Report") – WO 2004/092725 A1 is cited as an "X,P" reference in the Search Report against claims 1, 3-7, 10-11, 20-24, 33-35. WO 2004/092725 A1 was published on October 28, 2004, which is after Applicant's foreign priority date of July 01, 2004. Moreover, US 2007/0053790 A1, which is an English language equivalent of WO 2004/092725 A1 reveals that WO 2004/092725 A1 requires the two reagent portions (51,52) to be on opposite facing planes, not the same plane as claimed in claim 1. See the abstract; Figures 1-4, 9A-D; and specification paragraphs [0009] and [0066]. With regard to Applicant's independent claim 4, the facing arrangement of reagent portions in US 2007/0053790 A1 actually shortens the difference in time between the electron transfer reaction and the electron medium detection reaction, so the last limitation of claim 4 would not apparently be met. See US 2007/0053790 A1 specification paragraphs [0064]-[0067].

WO 02/33407 A1 is cited as an "X" reference against claims 1, 6, 10-11, 20, 23-24, 33-35, and as a "Y" reference against claims 7 and 21-22. Unlike the invention of Applicant's claim 1, in the embodiment of Figure 29 of WO 02/33407 A1 the reagent portion and the additional reagent portion are on different parallel planes. See page 8, lines 21-27. It should be noted that

element 52 in Figures 31 and 32 is a layer of highly reflective material, not a reagent portion. See page 16, lines 22-23. In the embodiment of Figures 27 and 28 although a reagent portion is provided upstream from a reagent portion in the detection zone there is no mention how these reagents are to interact, particularly whether electron transfer would occur as required by the last paragraph in claim 4. See page 08, lines 11-20 and page 15, lines 01-26. With regard to Applicant's independent claim 4, in the embodiment of Figures 29 and 30 of WO 02/33407 A1 the reagent layer (44) is before the introduction port for introducing the sample into the flow path,

Final Rejection

11. Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Nogueroles/
Primary Examiner, Art Unit 1795
March 19, 2010